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July 9, 2003

Public Information and Records Integrity Branch (PIRIB)
Information Resources and Services Division (7502C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Mall 2 - Room 119
1921 Jefferson Davis Highway
Arlington, VA 22202
Attention: Steven Knott

Dear Mr. Knott:

**SUBJECT: SYNGENTA INITIAL PUBLIC COMMENTS ON CD FOR
SCIENCE ADVISORY PANEL MEETING OF JULY 17, 2003 CONCERNING
ATRAZINE EPIDEMIOLOGY**

Enclosed please find 30 copies of a CD containing PDF files of publications and study reports relating to the subject SAP meeting. Syngenta is requesting that the documents be made available as soon as possible to the SAP members as background materials. The following briefly describes the documents and their content.

Syngenta's St. Gabriel Epidemiologic Study and Related Documents

- *Cancer Incidence Among Triazine Herbicide Manufacturing Workers* (MacLennan, P. et al., *J. Occ. Environ. Med.* 44: 1048-1058, 2002).
 - This is the most recent publication on the St. Gabriel worker study.
 - It is taken from, "A Follow-up Study of Cancer Incidence Among Workers in Triazine-Related Operations at the Novartis St. Gabriel Plant"
- *Use of Agriculture Pesticides and Prostate Cancer Risk in the Agriculture Health Study Cohort* (Alavanja, et al 2002)

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- *An Evaluation of the Report by Dr. Delzell et al., 2001 On "A Follow-up Study of Cancer Incidence Among Workers in Triazine-Related Operations at the Novartis St. Gabriel Plant" (Mandel, et al, 2002)*
- *Summary of Information on Potential Atrazine Exposure for 12 out of 17 Prostate Cancer Cases Reported by Delzell et. al. 2001(Breckenridge, 2002).*
This document was prepared in response to EPA's questions concerning estimates of atrazine exposure in the St. Gabriel manufacturing plant and is a preliminary effort to characterize degrees of exposure.
- *Protocol for a Case-Control Study of Prostate Cancer and Exposure to Atrazine.* This is a protocol that was prepared by Dr. Mandel as a follow-up to Dr. Delzell's 2001 report. This study is in progress and will be made available to the EPA when completed.

Other Publications on Atrazine Epidemiology Studies

- *A Review of Epidemiologic Studies of Triazine Herbicides and Cancer (Sakhiakumar and Delzell, 1997).*
- *"Atrazine and/or Triazine Herbicides Exposure and Cancer: An Epidemiologic Review" Neuberger, J.S. Agromedicine 3(2): 9-30, 1996*
- *"Epidemiology of Atrazine" Loosli, R. Reviews of Environmental Contamination and Toxicology 143: 47-57, 1995)*
- *Mortality Among Workers at Two Triazine Herbicide Manufacturing Plants (Sathiakumar 1995)*
- *Mortality Among Triazine Herbicide Manufacturing Workers (MacLennan, et. al, 2003)*

Background Toxicology Information

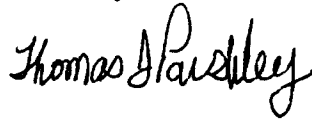
- *EPA Memorandum: Atrazine Toxicology Chapter of the Reregistration Eligibility Decision, Second Revision, Dated April 11, 2002 (Taylor, 2002), pages 54-55 excerpted).*
 - This document shows EPA's decision that atrazine is classified as "not likely to be carcinogenic to humans."
- *An Assessment of Developmental and Reproduction Studies on Atrazine in Rodents (Breckenridge, 2003).*

- This document contains all of the GLP studies that pertain to the lack of significant effects by atrazine in developmental and reproduction studies.
- *Assessment of the Potential Effects of Atrazine Administration on The Prostate Gland (Delzell and Stevens, 2000).* This document describes...
 - The basic anatomy and physiology of the human and rodent prostate,
 - Spontaneous Rate of Lesions/Susceptibility, Prostatitis,
 - Epidemiology and prostate cancer in humans,
 - Lack of effects in the prostate gland following the administration of atrazine in animal studies (rodents and dogs).

Regarding two documents included on the CD and noted above, that were provided to EPA as data volumes, Syngenta does not wish to claim as confidential under FIFRA Section 10, but does wish to retain the requirement that requestors complete the multinational affirmation statement as stipulated in Section 10(g). The two reports are Mandel et al, 2002 and Breckenridge, 2002.

Thank you for your assistance in this matter. Syngenta looks forward to participating in the upcoming SAP meeting on July 17, 2003. Please telephone Janis McFarland at (336) 632-2354 or myself at (336) 632-7207 if there are any questions concerning this submission or our presentation.

Sincerely,



Thomas J. Parshley
Senior Regulatory Product Manager
Regulatory Affairs

CC: Eric Olsen (EPA/SRRD)

Attachments

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